

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 14, 2004, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-6758, FAX: 301-827-6776, or e-mail: PerezT@cder.fda.gov. Please call the FDA Advisory Information Line at 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512538, for up-to-date information on this meeting.

Agenda: The committee will discuss the efficacy and safety of new drug application (NDA) #21-200, ZELNORM (tegaserod maleate), for the proposed

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indication of the treatment of patients with chronic constipation and relief of associated symptoms of straining, hard or lumpy stools, and infrequent defecation.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July **6, 2004**. Oral presentations from the public will be scheduled between approximately **1:30 p.m.** and **2:30 p.m.** Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July **6, 2004**, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

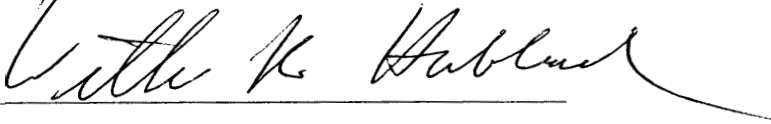
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Thomas H. Perez at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: June 7 2004

June 7, 2004.



William K Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 04-????? Filed ??-??-04;8:45 am]

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